JAN 22 2010

Section 3. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

3.1 Name, Address, Phone and Fax Number of the Applicant

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3.3 Application Correspondent

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Strategic Regulatory Solutions
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3.4 Date Prepared
December 21, 2009

3.4 Device Name

SiphonX® Gravitational Anti-siphon Device

3.5 Device Description

The SiphonX® Gravitational Anti-siphon Device is a siphon regulating accessory device used in the treatment of hydrocephalus.

SiphonX® Gravitational Anti-siphon Device is an implantable, single-use device. The SiphonX® Gravitational Anti-siphon Device consists of a plastic housing with integral inflow and outflow

channels that are separated by a conical valve seat. The housing contains a weight ball that rests upon a smaller, orifice-sealing ball. The device contains two silicone seals. Gravitational effect is provided by a weight ball which pushes on the valve sealing ball, under the effect of gravity, as the device transitions from a horizontal to a vertical position. The cerebrospinal fluid (CSF) flows in through the inlet connector, past the orifice-sealing ball and flows out by way of the outlet connector when the fluid pressure is greater than the sum of the pressure exerted by the weight ball and the operating pressure of the valve.

When the SiphonX® Gravitational Anti-siphon Device is in a horizontal position, no resistance to the flow is provided by the weight ball and orifice-sealing ball thereby allowing CSF to flow freely as regulated by the upstream shunt. On the contrary, when the SiphonX® Gravitational Anti-siphon Device is in a vertical position, maximum CSF resistance is applied as the weight ball presses on the orifice-sealing ball. The CSF is directed towards the orifice-sealing ball creating an opposing force to that which is generated by the weight ball. Upon sufficient CSF flow and combined valve pressure and Gravitational Anti-siphon Device pressure, CSF is able to push up the orifice-sealing ball and weight ball and flow through the outlet channel and connector.
The device will be distributed by itself or in combination with the Polaris® and Sophy® Pressure Adjustable valves and valve kits.

3.6 Device Intended Use

The SiphonX® gravitational anti-siphon device is designed to control the siphon effect during the treatment of hydrocephalus by shunting Cerebrospinal Fluid (CSF).

3.7 Substantial Equivalence Summary

The SiphonX® Gravitational Anti-siphon Device is substantially equivalent to the Shunt Assistant® siphon regulating device that is cleared for use in the Aesculap®-Miethke Shunt System (K011030) and Aesculap®-Miethke proGAV® Shunt (K062009). The predicate siphon - regulating device is distributed in kits as well as individually.
The SiphonX® device and the predicate utilize the same technology (Weight ball) to regulate the siphon effect.

3.8 Device Testing

The SiphonX® Gravitational Anti-siphon Device was subjected to laboratory testing to demonstrate device safety and efficacy. Testing included mechanical, functional and biological tests.

Functional tests were conducted based upon the requirements of international standard ISO/FDIS 7197:2006(E), Neurological implants- Sterile single use hydrocephalus shunts and components and ASTM F 647, Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurological Application. Results of the testing showed that the SiphonX® Gravitational Anti-siphon Device design is safe for its intended use.

The SiphonX uses the same materials as the SOPHYSA Sophy® Adjustable Pressure Valve (K013488) so biocompatibility test results performed on the Sophy® Adjustable Pressure Valve are considered to be transferable to the SiphonX device. The original biocompatibility studies

were conducted according to ISO 10993-1 standard and had demonstrated that the SOPHYSA Sophy® Adjustable Pressure Valve was biocompatible, and therefore the SiphonX is considered to be biocompatible. One slight difference between the devices is the presence of laser marking on the SiphonX. The impact of laser marking on biocompatibility was tested and successfully passed genotoxicity testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 22 2010

Sophysa SA
c/o Gustavo Kobrin
Application Correspondent for Sophysa SA
8502 E. Chapman Ave., #234
Orange, CA 92869

Re: K091328
Trade/Device Name: Siphon X Gravitational Anti-siphon Device
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 22, 2009
Received: December 24, 2009

Dear Mr. Kobrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091328

Device Name: SiphonX® Gravitational Anti-siphon Device.

Indications for Use:

The SiphonX® gravitational anti-siphon device is designed to control the siphon effect during the treatment of hydrocephalus by shunting Cerebrospinal Fluid (CSF).

Prescription Use ____√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091328